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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,968	08/26/2003	Helmut Borberg	07030.0004U2	7077

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EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
05/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/649,968	BORBERG ET AL.	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 has been amended to recite that the method step of treating the blood is "by differentially removing" high molecular weight protein from the subject. The specification as originally filed does not support differentially removing proteins from the blood. Further, the specification as originally filed does not provide a written description that reasonably conveys what applicant encompasses the step of differentially removing.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1 & 2 are rejected under 35 U.S.C. 103(a) as obvious over "*Plasmapheresis in the treatment of critical degree of ischaemia in diabetic and angiopathies of lower extremities*" (Georgadze et al.) in view of Malchesky et al. (4,350,156).

Georgadze et al. teaches that plasmapheresis may be used for the treatment of ischemia in the lower extremities of diabetics. It is disclosed that the plasmapheresis corrects the biochemical and coagulation parameters of the blood and thereby preserves the extremity from amputation in most patients. Plasmapheresis will remove protein, as disclosed in the article (see chart & body of article). The treatment of blood via plasmapheresis as treatment for a person diagnosed with diabetic ischemia of the foot since the foot is met since a foot is obviously part of the lower extremity. Such treatment would be beneficial to preserve the foot from amputation. Georgadze et al. substantially teaches the invention as claimed, except for specifically teaching that the

method to remove high molecular weight proteins and wherein the high molecular weight protein is lipoprotein cholesterol.

Malchesky et al. teaches of plasmafiltration of blood for the removal of high molecular weight (for example 100,000 Daltons) such as cholesterol-lipid complexes (i.e. lipoprotein cholesterol). It would have been obvious to one at the time of the invention, since the procedures of plasmapheresis of blood and plasmafiltration of blood are analogous fields of endeavor, to modify the method of Georgadze et al. to specifically remove high molecular protein, such as lipoprotein cholesterol, as taught by Malchesky et al. if desired since both teach of removing protein from the blood to achieve a therapeutic result.

4. Claims 1 & 2 are rejected under 35 U.S.C. 103(a) as obvious over "Seidel et al. (4,923,439) in view of Georgadze et al. ("*Plasmapheresis in the treatment of critical degree of ischaemia in diabetic and angiopathies of lower extremities*"). Seidel et al. discloses an extracorporeal method and apparatus for removing low density lipoproteins by using a plasma filter that precipitates low density lipoproteins from blood, thereby "differentially removing" the lipoproteins. Seidel et al. substantially teaches the invention as claimed, except for specifically teaching that the method to remove high molecular weight proteins is to treat a diabetic subject having ischemia of the foot.

Georgadze et al. teaches that plasmapheresis may be used for the treatment of ischemia in the lower extremities of diabetics. It is well known that plasmapheresis is a technique that utilizes a filter to remove substances from the blood. It would have been

obvious to one at the time of the invention, since the blood treatment procedures are analogous fields of endeavor, use the method of Seidel et al. to treat diabetic patients having ischemia of the foot, as taught Georgadze et al. to preserve the foot from amputation.

Response to Arguments

5. Applicant's arguments filed 1/16/2007 have been fully considered but are not persuasive.

6. With respect to the Rejection under 35 U.S.C. § 112, first paragraph, Applicant argues that "differentially removing" refers to "high molecular weight proteins" and that the as-filed application teaches "several plasma differential separation techniques" throughout the specification. Further, Applicant argues that the use of "plasma differential filtration" is described as passing plasma through a filter eliminating proteins according to the pore size of the membranes, further stating that it is recognized in the art that pore size of a membrane is related to the molecular weight of a substance retained. Finally, Applicant argues that one of skill in the art would recognize that this application teaches the use of filters with pore sizes that differentially remove high molecular weight proteins.

7. It is not clear that this differentially removing of high molecular weight proteins is only based on the pore size of a filter, since other methods of removing high molecular weigh protein may be used. It is also noted that Applicant also sets forth that "several plasma differential separation techniques" may remove high molecular weight protein in

the specification. Furthermore, applicant does not give specific information on the filter pore sizes, but rather only gives examples of filters by trade names (see paragraph [0032]). Therefore, it does not preclude one from having to do undue experimentation to determine what constitutes how to "differentially" remove protein from the blood.

8. In response to applicant's argument that there is no suggestion to combine the references Georgadze et al. and Malchesky, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both teach of plasmapheresis methods and are, therefore, from the same field of endeavor. Regarding applicant's argument that Georgadze et al. does not disclose the treatment of blood without the use of Rheopolyglukin (Page 6 of arguments), the step of removing low density lipoprotein cholesterol may be performed regardless of whether Rheopolyglukin is present.

9. In response to applicant's argument that there is no suggestion to combine the references Seidel et al. and Georgadze et al., the references are not silent on describing a method for treating ischemia of the foot, as Georgadze et al. discloses a methof of treating the lower extremeties, and Seidel et al. discloses the removal of low

density lipoproteins from blood. For the same reasons as the rejection of Georgadze et al. in view of Malchesky , it would have been obvious to one of ordinary skill in the art to combine these references, as both are related to the same field of endeavor.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
4/30/07

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER